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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,253	04/12/2004	Jennifer Lynne Reed	10271-112-999	5470

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,253	REED, JENNIFER LYNNE	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-168* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-141 and 143-168* is/are rejected.

7)☒ Claim(s) *142* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *May 1, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed May 1, 2006 has been entered.

   Claims 1-110 have been canceled.

   Claims 111-168 are newly added.

   Claims 111-168 are pending.

   Claims 111-168 are under consideration in the instant application as they read on the elected invention of Group I, an anti-IL-9 antibody, more particularly the 7F3com-2H2 antibody.

   The Examiner notes that none of the newly added claims are drawn to generic anti-IL-9 antibodies.

2. Newly added claims 111-146 and 148-168 appear to be entitled to the benefit of priority of USSN 60/462,259, filed April 11, 2003.

3. The rejections of record can be found in the previous Office Action, mailed November 29, 2005.

   This Office Action is in response to Applicant's amendment filed May 1, 2006.

   The text of those sections of Title 35 U.S.C. not included in this Office Action can be found in a prior action.

   Any rejection of record from the prior office action not restated below can be considered withdrawn in view of applicants cancellation of previously pending claims 1-110.

4. The information disclosure statement submitted on May 1, 2006 has been considered.

5. In view of the papers filed May 1, 2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Herren Wu, Ying Tang, Julian Davies and Jeffry D. Watkins.

6. It is apparent that the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913 is required to practice invention of claims **111, 113-115, 117-119, 121-123, 125-127, 143-145, 148, 149, 152, 154, 155-162 and 163-168**. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

   Given the disclosure and the claims encompassing the antibody produced by the cell line deposited as ATCC PTA-802 set forth in U.S. Patent No. **6,541,611**; the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to the antibody produced by the cell line deposited as ATCC PTA-802 appear to have been satisfied.

   Given applicant's provision of a statement regarding the permanence and availability of the biological material deposited as ATCC number "PTA-5913" on April 9, 2004, the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to the biological material deposited as ATCC number "PTA-5913" appear to have been satisfied.

   However, since the deposit was made after the earliest claimed priority date, i.e., April 11, 2003, if applicant wishes the claims which read on the biological material deposited as ATCC number "PTA-5913" to have the benefit of the earliest claimed priority date, applicant should submit a verified statement from a person in a position to corroborate the fact that the biological material deposited April 9, 2004 is the same as the biological material identified on pages 202-203 of USSN 60/462259, filed April 11, 2003, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b) and 2406.02.

7. The amendment filed May 1, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

   The change at position 202 in **Figure 9B** and the same change to **SEQ ID NO:28** of the sequence listing is not supported by the original disclosure because it is unclear if the statements appearing on page 14, 1st and 2nd paragraphs of applicants amendment and remarks were ***signed by someone in a position to corroborate the fact*** that the change at position 202 in figure 9B and the same change to SEQ ID NO:28 of the sequence listing are supported by the sequence of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913.

Applicant is required to cancel the new matter in the reply to this Office Action in the absence of a verified statement from a person in a position to corroborate the fact that the change at position 202 in figure 9B and the same change to SEQ ID NO: 47 of the sequence listing are supported by the sequence of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913, except if that person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified.

8. Claims **111-141, 143, 144, 146-149, 152, 153 and 155-164** are rejected under **35 U.S.C. § 112, 1st paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record put forth in the prior office action.

The instant claims are drawn to anti-IL9 "antibody" molecules which comprise one, two, three or four complementarity determining regions of defined sequence or any one, two, three or four complementarity determining regions of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913, and which may or may not be in a particular order.

The term "antibody" as used in the instant claims, given its broadest reasonable interpretation consistent with the instant specification, includes, among other things, "single domain antibodies", which is a molecule containing, for example, a heavy chain but not a light chain, and, "epitope binding fragments of any of the above. In particular, antibodies include immunoglobulin molecules and immunologically active fragments of immunoglobulin molecules, i.e., molecules that contain an antigen binding site." (see instant specification, page 30, paragraph [0084] and page 213, paragraph [0503]).

Applicant argues that the prior art contains examples of antibodies composed of less than 6 CDRs that have high affinity and antigen specificity and that methods for their production was known in the art.

Applicant's argument is not found persuasive essentially for the reasons of record set forth in the previous Office Action.

More particularly, as put forth in the prior office action, it is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three different complementarity determining regions, (CDRs 1-3), which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and

that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

For example, Janeway et al. teach that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (See Janeway et al., Immunobiology, 6th Ed., Garland Science, pp. 110-112 (2004), cited in the prior Office Action).

Thus, it is unlikely that the anti-IL-9 "antibody" molecules recited by the instant claims, which comprise one, two, three or four complementarity determining regions of defined sequence or any one, two, three or four complementarity determining regions of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913, and which may or may not be in a particular order, will have the required binding function. The specification provides insufficient direction or guidance regarding how to make antibodies as broadly defined by the claims.

Futhermore, applicant has not provided *objective evidence* to indicate that any of the instantly claimed "antibody" molecules, can bind IL-9. For example, applicant has not provided *objective evidence* to show that the **"single domain antibody"** recited in claim 153, which contains a heavy chain which comprises SEQ ID NOs:26,2 and 3 (as recited in claim 128), or in the alternative, a light chain which comprises SEQ ID NOs:62,65 and 20 (as recited in claim 135) **actually binds to IL-9**.

Undue experimentation would be required to produce the claimed invention commensurate with the scope of the claims from the written disclosure alone. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims **111-141, 143, 144, 146-153 and 155-166** are rejected under **35 U.S.C. § 112, 1st paragraph,** as containing subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the art that the inventor(s), at the time of the application was filed, had ***possession*** of the claimed invention.

A. "Antibodies" comprising less than 6 CDRs of a defined sequence/defined order: claims 111-141, 143, 144, 146-149, 152-153 and 155-164.

Claims 111-141, 143, 144, 146-149, 152-153 and 155-164 are drawn to anti-IL9 "antibody" molecules which comprise one, two, three or four complementarity determining regions of defined sequence or any one, two, three or four complementarity determining regions of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913, and which may or may not be in a particular order.

The term "antibody" as used in the instant claims, given its broadest reasonable interpretation consistent with the instant specification, includes, among other things, "single domain antibodies", which is a molecule containing, for example, a heavy chain but not a light chain, and, "epitope binding fragments of any of the above. In particular, antibodies include immunoglobulin molecules and immunologically active fragments of immunoglobulin molecules, i.e., molecules that contain an antigen binding site." (see instant specification, page 30, paragraph [0084] and page 213, paragraph [0503]).

Applicant argues that the specification and the prior art disclose, for example methods for making single domain antibodies, and that the disclosure combined with the knowledge in the art demonstrates that applicants were in possession of the claimed invention.

Applicant's argument is not found persuasive essentially for the reasons of record set forth in the previous Office Action.

There is insufficient written description in the specification as-filed for "antibody" molecules which comprise one, two, three or four complementarity determining regions of defined sequence or any one, two, three or four complementarity determining regions of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913, and which may or may not be in a particular order, that bind IL-9. The instantly claimed "antibodies" lack a common structure essential for their function, and the claims do not require any particular structure basis be shared by the instant "antibodies". The genus of the instantly claimed "antibodies" is therefore extremely large.

Futhermore, applicant has not provided *objective evidence* to indicate that any of the instantly claimed "antibody" molecules, can bind IL-9.

It does not appear based upon the instant specification that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the extensive variation permitted within the claimed genus.

B. "Antibodies" comprising a light/heavy chain encoded by the vector deposited as ATCC deposit No. PTA-5913 and *any* second light/heavy chain: claims 150, 151, 165 and 166.

Claims 150, 151, 165 and 166 are drawn to anti-IL9 "antibody" molecules which comprise the variable heavy/light chain encoded by the vector deposited as ATCC Deposit No. PTA-5913 which contain three complementarity determining regions (CDR) of defined sequence, with (claims 165/166) or without (claims 150/151) up to 3 amino acid substitution in each CDR, and further comprising **any** variable heavy/light chain domain of non-specified sequence.

Other than the specific examples shown in Table 1 (see instant specification pages 56-57), which appear to be closely related derivatives of a **single** variable light chain domain + heavy chain domain pair, there is insufficient written description of "antibody" molecules which comprise the variable heavy or light chain domain encoded by the vector deposited as ATCC Deposit No. PTA-5913 further comprising **any** variable heavy or light chain domain of non-specified sequence which retains the ability to bind IL-9.

As taught by Janeway et al., *ibid*, the immune system generates antibodies of different specificities by combining **different** variable heavy or light chains (combinatorial diversity), wherein the complementarity determining regions from **both** chains contribute to antigen binding specificity. As is well known in the art, through this recombination process, hundreds of millions of different antibodies with different specificities can be obtained.

It does not appear based upon the disclosure of Table 1 alone that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the claimed genus in view of the extensive potential variation permitted within the genus of **any** variable heavy/light chain domain of non-specified sequence.

The paragraphs that follow apply equally to sections **A** and **B** above.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997).

The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

10. This is a **New Grounds of Rejection** necessitated by applicant's amendment to the specification and sequence listing. Claim 147 is rejected under **35 U.S.C. § 112, 1st paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

    Claim 147 recites SEQ ID NO:28, which applicants have amended as described in the objection to the specification in section 3B above. For the same reasons given in the objection to the specification in section 3B above, claim 147 is rejected as containing matter which was not originally disclosed in the instant specification as filed.

    This rejection can be overcome by providing a verified statement from a person in a position to corroborate the fact that the change at position 202 in figure 9B and the same change to SEQ ID NO: 47 of the sequence listing are supported by the sequence of the antibody encoded by the vector deposited as ATCC deposit No. PTA-5913, except if that person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified.

11. No claim is allowed. However, claim 142 is objected to as being dependent upon a rejected base claim, and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
July 13, 2006

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